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REMARKS

Claims 1-19, 21-35 and 39-57 are pending in the subject application. Claims 1-3 and 10 are amended. Claim 9 is canceled, without prejudice. Applicants submit that the amendments introduce no new matter, support therefore being found throughout the application as originally filed (e.g. see page 14, lines 12-19; Fig. 6). Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

1. 35 U.S.C. 102 Rejections

Drasner et al.

Claims 1-4, 8, 12, 16, and 25-33 are rejected under 35 U.S.C. 102(b) over Drasner et al (USPN 5,234,406).

Applicants respectfully traverse.

Applicants recite, in claim 1, a microcatheter system for infusion of a solution into a retinal vein. Applicants' microcatheter system remains within the retinal vein during the infusion without an external holding device for at least a period of time required for a bolus injection. The microcatheter system comprises a flexible cannula mounted in a second cannula, wherein the flexible cannula and the second cannula form an infusion fluid path. As set out, the flexible cannula has an outer diameter less than about 100 μm. At least a portion of the second cannula is disposed within the eye when the microcatheter system is placed within the eye for infusion into a retinal vein, while at least a portion of the flexible cannula is disposed within the retinal vein when the microcatheter system is placed within the eye for infusion into a retinal vein.

Applicants recite, in claim 2, a microcatheter system comprising a flexible cannula for insertion into a retinal vein lumen and a second cannula. The flexible cannula has an outer diameter less than about 100 μm. The second cannula is disposed within the eye when the flexible cannula is inserted into a retinal vein. The flexible cannula is at least partially encased in the second cannula, and the flexible cannula and the second cannula form an infusion fluid path. Solution is infused into the retinal vein lumen through the flexible cannula and the flexible

cannula remains within the retinal vein lumen during the infusion without an external holding device for at least a period of time required for a bolus injection.

Applicants recite, in claim 3, a microcatheter system comprising a flexible cannula for insertion into a retinal vein lumen and a second cannula. The flexible cannula has an outer diameter less than about 100 μm. The second cannula is disposed within the eye when the flexible cannula is inserted into a retinal vein. The flexible cannula is mounted in the second cannula, and the flexible cannula and the second cannula form an infusion fluid path. A solution is infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding device.

Applicants respectfully submit that Drasner at least fails to teach or suggest a flexible cannula mounted in a second cannula, a flexible cannula having an outer diameter less than about 100 μm, or a second cannula and a flexible cannula provided such that the second cannula is disposed within the eye when the flexible cannula is disposed within a retinal vein.

The Office asserts that Drasner "discloses a flexible cannula (12) mounted in a second cannula (14)" pointing to figure 1.

Applicants respectfully disagree. Drasner describes a method and system for delivery of anesthetics to the spine. Drasner's system includes a distal catheter section 12 and a proximal tube extension 14. The distal catheter section 12 is connected to the proximal tube extension 14 via a hub 30 that can provide permanent or detachable connection (see col. 2, lines 53-64). In an alternate embodiment, the catheter section 12 and the tube section can be formed from a single extrusion (see col. 3, lines 3-4). Nowhere does Drasner teach or suggest that catheter section 12 is mounted in the tube extension 14.

Further, Drasner describes a distal catheter section 12 (which the Office asserts is equivalent to Applicants' flexible cannula) having a lumen diameter ranging from 28 gauge (0.0149", 0.38mm) to 32 gauge (0.0097", 0.25mm). The outer diameter of the distal catheter

section 12 is even larger than the lumen. Drasner's device is specifically adapted for insertion through a patient's back and into the spinal area. As such, Drasner's device provides an appropriately sized catheter section 12. In particular, Drasner's catheter section 12 has an outer diameter that is least 2.5 times as large as Applicants' device. Drasner's device could not be used for insertion into a patient's eye and insertion into the retinal vein within the eye. Further, Drasner's device could not be modified so as to provide an outer diameter set forth by Applicant because such a modification would render the device of Drasner unsuitable for its intended use of delivering anesthetics to the spine at a desired flow resistance and accuracy (see col. 4, lines 15-24) for desired periods of time with proper distribution of anesthetic solution (see col. 4, line 64 – col. 5, line 4).

Further, Drasner describes a distal catheter section 12 (which the Office asserts is equivalent to Applicants' flexible cannula) having a length ranging from 15-25 cm. This length is specifically provided for insertion through a patient's back and into the spinal area. Thus, the Drasner device could not be provided such that the proximal tube section 14 is disposed within an eye when the catheter section 12 is disposed within a retinal vein of the eye. A typical human eye is about 2.5 cm in length and, thus, if the tube 14 is disposed within the eye, then the catheter section 12, which extends from the tube 14 a length of 15-25 cm, could not fit within the eye. Further, Drasner's device could not be modified so as to provide a proximal tube section 14 that is disposed within an eye when the catheter section 12 is disposed within a retinal vein of the eye because such a modification would render the device of Drasner unsuitable for its intended use of delivering anesthetics to the spine by insertion of the device through conventional spinal needles (see col. 3, lines 35-38).

Thus, Drasner clearly fails to teach each an every element of Applicants' claim 1. Accordingly, claims 1-3 are not anticipated by Drasner. Claims 4, 8, 12, 16, and 25-33 depend from claims 1-3 and, likewise, are not anticipated by Drasner. Reconsideration and withdrawal of the rejection is respectfully requested.

DeCamp et al

Claims 1-7, 12, 14-19, and 25-33 are rejected under 35 U.S.C. 102(b) over DeCamp et al (USPN 5,792,099).

Applicants respectfully traverse. DeCamp at least fails to teach or suggest a flexible cannula mounted in the second cannula, the flexible cannula having an outer diameter less than about 100 μm.

DeCamp describes a syringe for insertion of viscoelastic material into an eye. DeCamp's syringe comprises a cannula 24 that includes a needle 26. The needle includes a first large diameter portion 36 (which the office asserts is equivalent to Applicants' second cannula) and a second smaller diameter portion 40 (which the office asserts is equivalent to Applicants' flexible cannula). The first portion 36 is between 18 gauge (0.0478", 1.21 mm) and 23 gauge (0.0269", 0.68mm) (see col. 4, lines 42-44). The second portion 40 is between 23 gauge (0.0269", 0.68mm) and 30 gauge (0.012", 0.31mm)(see col. 4, lines 44-47). DeCamp's device is provided with particularly described structural features to allow for insertion of viscoelastic material into an eye (col. 4, lines 17-22). As set out, it is difficult to insert viscoelastic material into the eye due to its viscosity. Insertion through conventional syringes is limited due to the needle gauges and required pressures required to obtain desirable flow of material through such needles (see col. 1, lines 44-62). Thus, DeCamp provides a needle having two different portions with different diameters. The design and size of the needle portions is an important aspect in establishing flow of viscoelastic material therethrough. In particular, DeCamp provides a second smaller diameter portion 40 having an outer diameter that is at least 3 times as large as Applicants' device. Further, DeCamp could not be modified to provide smaller diameters recited by Applicants because the viscosity of materials delivered by DeCamp (5,000 – 60,000 cp, as set out, e.g., in col. 4, lines 12-22) could not be delivered by a cannula having such a size. Such a modification would render DeCamp unsuitable for its intended purpose of delivering viscoelastic material into an eye.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over DeCamp. Claims 4-7, 12, 14-19, and 25-33 depend from claims 1-3 and, likewise, are patentable over DeCamp.

Grinblat et al

Claims 1-7, 12, 14-16, 19, 21, and 23-33 are rejected under 35 U.S.C. 102(b) over Grinblat et al (USPN 5,545,153).

Applicants respectfully traverse. Grinblat at least fails to teach or suggest a flexible cannula mounted in the second cannula, the flexible cannula and the second cannula forming an infusion fluid path, or the flexible cannula having an outer diameter less than about 100 μm.

Grinblat describes an illumination and infusion system that includes a tube 26 having a plate member 28 at its distal end. Extending from the other side of the plate member 28 is a cannula portion 29. The plate member is adapted to be sewn to the eyeball at the start of the operation. An optical fiber 19 fits through and extends beyond the free end point 30 of the cannula 29.

According to Grinblat, the cannula portion 29 (which the Office equates to Applicants' second cannula) has an outer diameter of 0.9mm and a length from 3.5-6.0mm (see col. 4, lines 14-21). The optical fiber 19 (which the Office equates to Applicants' flexible cannula) has an outer diameter of 0.5 mm (for small models) and 0.73-0.75 mm (for larger models) (see col. 3, lines 51-54). Thus, Grinblat describes an optical fiber that is at least 5-7 times as large as Applicants' flexible cannula.

Further, Grinblat's optical fiber 19, like conventional optical fibers, is formed of a solid core with a thin cladding surrounding the core. Thus, Grinblat's optical fiber 19, which is solid and has no lumen, does not form an infusion fluid path with cannula portion 29.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over Grinblat. Claims 4-7, 12, 14-16, 19, 21, and 23-33 depend from claims 1-3 and, likewise, are patentable over Grinblat.

Le et al

Claims 1-4, 12-16, and 25-33 are rejected under 35 U.S.C. 102(b) over Le et al (USPN 6,355,027).

Applicants respectfully traverse. Le at least fails to teach or suggest a flexible cannula and a second cannula, wherein least a portion of the second cannula is disposed within the eye when the cannula is inserted into a retinal vein.

Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief. The catheter tube 16 (which the Office equates to Applicants' flexible cannula) measures 100 to 160 cm long from the strain relief 14 (which the Office equates to Applicants' second cannula). The catheter tube 16 includes a distal region of flexibility 20, a mid region of flexibility 22, and a proximal region of flexibility 24, wherein the distal region 20 measures from 10-30 cm, the mid region measures from 10-30 cm, and the proximal region measures from 80-100 cm (col. 2, lines 45-58). This design is specifically adapted to provide a microcatheter that can be inserted and navigated through long tortuous pathways without the catheter bending or kinking.

Thus, the Le device could not be provided such that the strain relief 14 is disposed within an eye when the catheter tube 16 is disposed within a retinal vein of the eye. If the strain relief of Le's device 14 is disposed within the eye, then the catheter tube 16, which extends from the strain relief 14 a length of 100 to 160 cm, could not fit within the eye (which is about 2.5 cm in length). Further, Le's device could not be modified so as to provide a strain relief 14 and a catheter tube 16 such that the strain relief 14 is disposed within an eye when the catheter tube 16

is disposed within a retinal vein of the eye because such a modification would render the device of Le unsuitable for its intended use of navigating through long tortuous pathways.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over Le. Claims 4, 12-16, and 25-33 depend from claims 1-3 and, likewise, are patentable over Le.

2. 35 U.S.C. 103 Rejections

DeCamp

Claim 8 is rejected under 35 U.S.C. 103(a) over DeCamp. Applicants respectfully traverse for the reasons set forth above.

As set out, DeCamp describes a syringe for insertion of viscoelastic material into an eye. DeCamp's syringe comprises a cannula 24 that includes a needle 26. The needle includes a first large diameter portion 36 having a diameter between 18 gauge (0.0478", 1.21 mm) and 23 gauge (0.0269", 0.68mm), and a second smaller diameter portion 40 having a diameter between 23 gauge (0.0269", 0.68mm) and 30 gauge (0.012", 0.31mm)(see col. 4, lines 44-47). DeCamp at least fails to teach or suggest a second smaller diameter portion 40 mounted in the first large diameter portion 36, the second smaller diameter portion 40 having an outer diameter less than about 100 μm. Rather, DeCamp's second smaller diameter portion 40 has a diameter that is at least three times as large as Applicants' device.

Further there is no suggestion or motivation to modify DeCamp's device to provide a second smaller diameter portion 40 that is three times smaller than the lowest range taught by DeCamp. DeCamp's device is provided with particular structural features to allow for insertion of viscoelastic material into an eye (col. 4, lines 17-22). As set out, it is difficult to insert viscoelastic material into the eye due to its viscosity. Insertion through conventional syringes is limited due to the needle gauges and required pressures required to obtain desirable flow of material through such needles (see col. 1, lines 44-62). Thus, DeCamp provides a needle having two different portions with different diameters. The design and size of the needle portions is an

important aspect in establishing flow of viscoelastic material therethrough. Modification of DeCamp's second smaller diameter portion 40 to have an outer diameter that is at least 3 times smaller than the size taught by DeCamp would render the DeCamp device unsuitable for its intended purpose because the viscosity of materials delivered by DeCamp (5,000 – 60,000 cp, as set out, e.g., in col. 4, lines 12-22) could not be delivered by a cannula having such a size.

Accordingly, claim 8 (which depends from claims 1-3) is patentable over DeCamp.

Le and Drasner

Claims 8-11 and 17-18 are rejected under 35 U.S.C. 103(a) over Le and Drasner. Applicants respectfully traverse.

As set forth above, Drasner describes a method and system for delivery of anesthetics to the spine. Drasner's system, thus, includes a distal catheter section 12 and a proximal tube extension 14 specifically designed for such delivery. Drasner at least fails to teach or suggest a flexible cannula mounted in the second cannula, a flexible cannula having an outer diameter less than about 100 μm, or a second cannula and a flexible cannula provided such that the second cannula is disposed within the eye when the flexible cannula is disposed within a retinal vein.

Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief specifically designed for such insertion and navigation. Le at least fails to teach or suggest a flexible cannula and a second cannula, wherein least a portion of the second cannula is disposed within the eye when the cannula is inserted into a retinal vein.

One of ordinary skill would not have been motivated to combine Drasner and Le. Drasner's device is specifically adapted to deliver anesthetics to the spine, while Le is specifically adapted for insertion into and through tortuous pathways. Further, even if Drasner and Le could be combined, neither Drasner nor Le teach or suggest Applicants' device

comprising a flexible cannula and a second cannula, wherein least a portion of the second cannula is disposed within the eye when the cannula is inserted into a retinal vein.

As set forth above with respect to Drasner, a typical human eye is about 2.5 cm in length and, thus, if the tube 14 of Drasner is disposed within the eye, then the catheter section 12, which extends from the tube 14 a length of 15-25 cm, could not fit within the eye. Further, Drasner's device could not be modified so as to provide a proximal tube section 14 that is disposed within an eye when the catheter section 12 is disposed within a retinal vein of the eye because such a modification would render the device of Drasner unsuitable for its intended use.

As set forth above with respect to Le, a typical human eye is about 2.5 cm in length and, thus, if the strain relief 14 of Le is disposed within the eye, then the catheter tube 16, which extends from the strain relief 14 a length of 100 to 160 cm, could not fit within the eye. Further, Le's device could not be modified so as to provide a strain relief 14 that is disposed within an eye when the catheter tube 16 is disposed within a retinal vein of the eye because such a modification would render the device of Le unsuitable for its intended use.

Thus, no combination of Drasner and Le would provide Applicant's device. Still further, any modification of Drasner and Le would render the modified devices unsuitable to be used as intended.

Accordingly, claims 8-11 and 17-18 (which depend from claims 1-3) are patentable over Drasner and Le.

Le and Applicants' Own Disclosure

Claims 19 and 21-23 are rejected under 35 U.S.C. 103(a) over Le in view of Applicants' own disclosure.

Applicants respectfully traverse.

As set forth above, Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief specifically designed for such insertion and navigation. Le at least fails to teach or suggest a flexible cannula and a second cannula, wherein least a portion of the second cannula is disposed within the eye when the cannula is inserted into a retinal vein. If the strain relief 14 of Le is disposed within the eye, then the catheter tube 16, which extends from the strain relief 14 a length of 100 to 160 cm, could not fit within the eye (which is about 2.5 cm in length). Further, Le's device could not be modified so as to provide a strain relief 14 that is disposed within an eye when the catheter tube 16 is disposed within a retinal vein of the eye because such a modification would render the device of Le unsuitable for its intended use.

Thus, modification of Le in view of Applicants' own disclosure would render the modified device of Le unsuitable to be used as intended.

Accordingly, claims 19 and 21-23 (which depend from claims 1-3) are patentable over Le in view of Applicants' own disclosure.

Le and Castora

Claims 34-35 are rejected under 35 U.S.C. 103(a) over Le in view of Castora (USPN 5,947,296).

Applicants respectfully traverse.

As set forth above, Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief specifically designed for such insertion and navigation. Le at least fails to teach or suggest a flexible cannula and a second cannula, wherein least a portion of the second cannula is disposed within the eye when the cannula is inserted into a retinal vein. If the strain relief 14 of Le is disposed within the eye, then the catheter tube 16, which extends from the strain relief 14 a length of 100 to 160 cm, could not fit within the eye (which is about

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2.5 cm in length). Further, Le's device could not be modified so as to provide a strain relief 14 that is disposed within an eye when the catheter tube 16 is disposed within a retinal vein of the eye because such a modification would render the device of Le unsuitable for its intended use.

Castora is merely cited as describing a catheter kit with multiple catheters packaged in one kit. Castora does not teach or suggest Applicants' microcatheter systems with the above noted-deficiencies set forth with respect to Le. Further, even if Castora did provide such deficiencies, one would not have been motivated to combine and modify Le and Castora to provide Applicants' claimed microcatheter because such modification would render the modified device unsuitable to be used as intended.

3. Allowable Subject Matter

Applicants appreciate the Office's notification that claims 39-57 are allowed.

CONCLUSION

It is believed that the application is in condition for immediate allowance, and Applicants respectfully request early favorable action by the Examiner.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Dated: September 5, 2006

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